REMARKS

Claims 1-21 and 23-35 are pending at the time of this action. Reconsideration and allowance of the above-referenced application are respectfully requested.

Rejection Under 35 U.S.C. 112

Claim 1 stands rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The examiner alleged that the application does not disclose the deployment of two separate structures as claimed in claim 1. Applicants respectfully disagree. Several sections of the specification provide written description regarding the deployment of two separate structures. For example, paragraph [0180] (U.S. Publication No. 20050033446) states "other techniques for more directly modifying the leaflets or other supporting structures of the atrioventricular valves will be described in this section. These techniques may be utilized either with or without the valve grasping and/or coaptation and adjustment techniques described above." Prior to paragraph [0180], the specification provided examples of structures that hold the valve leaflets together. In sections subsequent to paragraph [0180], the specification provides examples of additional structures that can be deployed on or the annulus of the heart valve. Paragraph [0180] explicitly states that the additional structures "may be utilized either with or without the valve grasping and/or coaptation and adjustment techniques described above." Thus, the specification provides explicit support for the deployment of two separate structures as claimed in claim 1.

In addition, at least Paragraphs [0019], [0027], [0031], [0034], [0038], [0039] and [0137] of the specification provide further written description of the deployment of two separate structures as claimed in claim 1. Applicants note that the cited paragraphs are not the only sections of the specification that provide written description of the recitations of claim 1 and that there are additional sections of the specification that provide further written description. Applicants have highlighted (with bolded font) certain cited paragraphs of the disclosure for the convenience of the examiner.

Paragraph [0038]: Systems according to the present invention comprise a guide catheter configured to pass from the remote vasculature of a patient to a position within the heart adjacent to a target atrioventricular or other cardiac valve. **The systems further comprise an interventional catheter configured to pass through the guide catheter and to engage the atrioventricular or other cardiac valve and/or associated cardiac structures and an interventional tool on the interventional catheter adapted to modify the atrioventricular or other cardiac valve leaflets, valve annulus, valve chordae or papillary muscles to reduce regurgitation.** In particular, the guide catheter can be configured for either an antegrade or retrograde approach to the mitral valve, as described above. The guide catheter may further comprise a stabilizing element for engaging tissue within the heart to reduce relative movement between the guide catheter and the tissue while the heart remains beating. The structure can be any of the cages, wires, or the like, which have previously been described in connection with the method. **Additionally, the interventional catheter may also comprise a stabilizing element for engaging a tissue structure within the heart to reduce relative motion between the interventional catheter and the tissue. The stabilizing element can also be an expansible cage, steering wires, or the like and may include vacuum and/or surface finishes to enhancing coupling. Specific interventional tools include** suturing devices, stapling devices, clip-applying devices, radiofrequency electrodes, surgical adhesive applicators, **annuloplasty rings**, and the like.

Paragraph [0039]: Typically, the stabilization mechanisms will be adapted to engage **at least one** tissue structure selected from the group consisting of the interatrial septum, the atrial wall, the valve annulus, the valve commissures, the valve chordae, and the papillary muscles. In view of the foregoing, Applicants submit that the application satisfies the

requirements of 35 U.S.C. 112. Accordingly, Applicants respectfully submits that the rejection under 35 U.S.C. 112 should be withdrawn.

Rejections under 35 U.S.C. §102

Claims 11-16, 18, 20, 21, 24, 26, 27, 30, and 32-35 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by US Patent Number 6,269,819 to Oz. However, Oz fails to disclose or suggest every element of the claims.

For example, Oz fails to disclose or suggest implanting an *annuloplasty device* from a catheter at the heart valve as recited in dependent claims 11 and 21. As stated in the present application at paragraph [0006], valve annuloplasty is generally the implantation of a mechanical support ring or other structure to strengthen the valve annulus. Oz fails to disclose any such "annuloplasty device." The examiner cited column 2, lines 47-54 of Oz as disclosing an "annuloplasty device." Applicants respectfully disagree with the Examiner's characterization of an "annuloplasty device" in the Oz disclosure. At column 2, lines 47-54, Oz describes a fastener either integrally attached to a grasper or as a separate device to "securely hold the leaflets in place after the grasper has been released." In the cited section, there is no disclosure whatsoever of an annuloplasty device or even the valve annulus.

The Examiner also cites element 102 of Figure 13 as disclosing an "annuloplasty device." Figure 13 is an embodiment of a grasper and coil fastener for fastening valve leaflets. Oz describes element 102 as a coil fastener that "advances in a spiral mode piercing leaflets in multiple locations as coil is advanced into its final position." (Oz, Col. 5:46-55.) Again, there is no disclosure in Figure 13 of an annuloplasty device or even the valve annulus.

Thus, Oz fails to disclose or suggest every element of claims 11 and 21. Applicants respectfully submit that the rejection of claims 11 and 21 under 35 U.S.C. 102 should be withdrawn. Claims 12-16, 18, 20, 24, 26, 27, 30, and 32-35 all depend from claim 1 or claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claims 1 and 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Oz.

For example, amended claim 34 recites that holding the leaflets of the valve together is accomplished by linking opposed chordae of the valve leaflets together using a device that

directly contacts the opposed chordae. Oz makes no mention whatsoever of linking opposed chordae of the valve leaflets together using a device that directly contacts the opposed chordae. The examiner argued that Oz discloses linking opposed chordae of the valve leaflets. In support of this argument, the examiner stated that "it is known that the chordae are part of the leaflets..." The art cited by the examiner explicitly contradicts this assertion. Oz describes the mitral valve apparatus at col. 1:46-51. There Oz states: "The components of the mitral valve assembly include the mitral valve annulus; the anterior leaflet; the posterior leaflet; two papillary muscles which are attached at their bases to the interior surface of the left ventricular wall; and multiple chordae tendineae, which couple the mitral valve leaflets to the papillary muscles." It is clear from this passage, that the chordae tendineae are separate components, and thus distinct from, the mitral valve leaflets. Thus, Oz fails to disclose the step of linking opposed chordae of the valve leaflets together using a device that directly contacts the opposed chordae, which is different from simply attaching the valve leaflets together.

Rejection of Claims under 35 U.S.C. §103

The examiner rejected claims 1-10 under 35 U.S.C. §103(a) as allegedly being unpatentable over Oz in view of US Patent Number 6,143,024 to Campbell. As acknowledged by the examiner, Oz fails to teach deploying a first structure from a catheter on or near an annulus of the heart valve. The examiner asserted that it would have been obvious to deploy the ring device of Campbell via the catheter taught by Oz. However, Oz teaches away from delivering a ring device to the annulus of the heart valve via a delivery catheter. Oz teaches that annuloplasty (deployment of a structure on the annulus) leads to "deteriorating ventricular performance." Specifically, at column 2, lines 4-14, Oz states:

> [R]ecent studies performed by the inventors (Umana et al., Surg Forum 1997) have revealed that posterior ring annuloplasty causes changes in ventricular geometry that lead to paradoxical movement of the normal papillary muscles, further deteriorating ventricular performance. In contrast, the "bow-tie" repair in which the anterior and posterior leaflets of the mitral valve are fixed in opposition appears to enhance annular contractility while preserving ventricular architecture. This has resulted in improved postoperative ventricular function almost uniformly.

Oz distinguishes annuloplasty from "bow-tie" repair in which a structure is deployed on the valve leaflets, not on the annulus. Oz therefore teaches away from deploying a structure on or adjacent the annulus.

Moreover, the combination of Oz with Campbell does not result in the method of claim 1. The device disclosed in Oz is structurally unsuited for deploying a structure on or near the annulus. Rather, the Oz device is a grasper that grabs and coapts the leaflets. The examiner has provided no basis as to how such a grasper could be used in a method that involves the step of deploying a ring structure on or near the annulus, as recited in claim 1. Applicants request that the examiner explain how the grasping device in Oz could be used to place a first structure on or near the annulus as recited in claim 1.

In view of the foregoing, Applicants submit that the rejection under 35 U.S.C. 103 should be withdrawn. Claims 2-10 depend from claim 1 and are patentable based on their dependence on claim 1 as well as on their own merit.

For example, claim 4 recites deploying the first structure such that the first structure mounts onto an atrial side of the annulus. As discussed in the previous office action response, Oz does not disclose deploying a structure that mounts onto an atrial side of the annulus. The examiner cited Oz at column 7, lines 51-58 in rejecting claim 4. However, the cited section of Oz makes no mention whatsoever of deploying a structure such that the structure mounts onto an atrial side of the annulus. The examiner failed to provide any explanation as to how the cited section of Oz discloses deploying a structure such that the structure mounts onto an atrial side of the annulus. As discussed in the previous response, the cited section of Oz describes a technique wherein the grasper enters the atrium via an atrial stab incision, crosses the valve into the ventricle, then reverts back toward the valve while in the ventricle. A suturing device is then applied to the leaflets "just as in the transventricular approach", which means that the suturing device attaches to the leaflets in the ventricle, not in the atrium.

In response to Applicants' arguments that Oz does not disclose deploying the first structure such that the first structure mounts onto an atrial side of the annulus, the examiner argued in paragraph 19 of the office action that "Oz shows the leaflets are grabbed and a clip is

attached at the point the leaflets are grabbed in Figure 13." Applicants' respectfully submit that the examiner's argument fails to address how Oz discloses or suggests deploying a structure such that the structure mounts onto an atrial side of the annulus. Figure 13 merely shows a device grasping the leaflets 96, which are located on the ventricular side of the annulus not on the atrial side of the annulus. Moreover, the explanation of Figure 13 in Oz (column 5, lines 46-55) provides no disclosure of deploying a structure such that the structure mounts onto an atrial side of the annulus. Applicants respectfully remind the examiner that the burden is upon the examiner to show how the cited reference discloses the claim limitation. Accordingly, Applicants respectfully request that the examiner provide some explanation other than a blanket statement as to how Oz discloses or suggests deploying a structure such that the structure mounts onto an atrial side of the annulus.

Claim 8 recites that holding the leaflets of the valve together is accomplished by linking opposed chordae of the valve leaflets together. Neither Oz nor Campbell disclose or suggest linking opposed chordae of the valve leaflets together. Neither reference has any discussion of linking the chordae.

Conclusion

It is believed that all of the pending claims have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Moreover, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

In view of the amendments and remarks herein, Applicants believe that all pending claims are in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with other positions of the Examiner that have not been explicitly

contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims.

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Respectfully submitted,

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